Quarterly Progress Report

Technical and Financial

Hypoxia, Monitoring, and Mitigation System

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S. J. Mahoney, Principle Investigator

Athena GTX, Inc.
Des Moines, IA

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2200 Gannett Avenue
Des Moines, IA 50321

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14. ABSTRACT
The HAMS program is progressing as expected with no technical issues to report. Partial FY2013/FY2014 funding remains an issue. Additional funds are need in March 2014 to continue the program. Tasks 1, 2 and 3 have been completed and Task 4 has started. The baseline parametric algorithm to predict %O2 saturation and aircrew state and the modification of the USN Consciousness Model to predict LOC due to altitude induced hypoxia remain as viable approaches moving into Task 4 - BETA Software Development/Definition.

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1.0 Summary

This quarterly progress report discusses the technical and financial program status for the period of November 2013 through January 2014. This is the last quarterly report before the final report on the program.

The Hypoxia Monitoring, Alert and Mitigation System (HAMS) program is progressing as expected with no technical issues to report. Partial FY2014 program funding remains an issue, and additional funding is needed in March of 2014 to continue the effort without significant impact to the program.

The program consists of four baseline tasks and one optional task:

1. Preliminary Research and Documentation
2. Develop Parametric Predictive Models
3. Algorithm Development and Refinement
4. BETA Model Software Development/Definition
5. *Concept System Refinement (Option)*

Work has been completed or started on Tasks 1, 2, 3 and 4. The Task 5 option (not yet exercised) would begin in June 2014.

The concentrated effort on the literature search activity (Task 1) has been completed. . Reasonably so, this task really never ends as new works constantly will be published or become available through professional connections. A File Transfer Protocol (FTP) site has been created to share references and data among the team members and Office of Naval Research (ONR). As data and additional information becomes available or uploaded to the FTP site we will address them as necessary.

The baseline parametric hypoxia modeling effort (Task 2) has been completed. A model to predict %O_2 saturation, aircrew state, alveolar pressure of oxygen (PaO_2) and alveolar pressure of carbon dioxide ($PaCO_2$) has been converted over to the C programming language. This will allow the algorithm to eventually run on a micro-controller. Additionally the time based algorithms have been adjusted to better represent the physiological response of the human to high altitude hypoxic events.

The conversion of the United States Navy (USN) Consciousness Model (Task 3) has been completed. Initial verification and sensitivity analysis has shown positive results and the code has been reduced to a size and complexity that will run on a modest microcontroller. The addition of a hypoxia component to the acceleration component of the model has demonstrated good results. Model and threshold refinement will continue with additional data sets in Task 4.

The final baseline task (BETA Model Software Development/Definition – Task 4) has been started. Software algorithms will be developed through three sequential iterations that will progressively refine a prediction for hypoxia and near-hypoxia conditions. The focus on implementation in a memory-limited, bit-constrained microcontroller will remain a top priority. For each iteration the algorithms and software will be evaluated using existing data.

We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract.

2.0 Introduction

Special Notice 13-SN-0003 outlined a research thrust entitled “Hypoxia Monitoring, Alert and Mitigation System” (HAMS) that was launched under the ONRBAA13-001. The desired features of the Hypoxia Monitoring, Alert, and Mitigation System were to predict/detect/warn warfighters of impending hypoxic events based on individual physiological, environmental, and cognitive monitoring. The stated goal was to provide optimal protection of military personnel and equipment through intelligent monitoring and adaptive modeling that accounted for individual differences in tolerance and provided timely notification/warning aids so personnel could take corrective action before compromise or loss. The team of Athena GTX (Athena) and Criterion Analysis Incorporated (CAI) collaborated, proposed and won an award under this effort.

This quarterly progress report discusses the technical and financial program status for the period of November 2013 through January 2014. It is intended to inform the Program Officer and Administrative Contracting Officer of the technical and financial progress of the HAMS program. This is the last quarterly report before the final report on the program.

This algorithm development effort and the approach taken under this project is within the context that the algorithms developed will eventually need to run on a “fieldable” solution. Consequently the focus will be on algorithms that can run on micro-controller based platforms. As technology evolves from the laboratory into actual high altitude environments and is then coupled to stress of military operations the complexity of the issues this program addresses can be realized. Previous efforts to date have showed that attempting to reliably peer into the brain from the scalp surface through the skull with EEG and f-NIRS is neither comfortable nor feasible in a dynamic laboratory/simulator environment much less in an aircraft; and hence, in our experience, remains suspect for operational use. Perhaps this program will deliver such a solution; perhaps it is not feasible with today’s technology. This by no means concludes that the technologies are not innovative or interesting or that they do not show promise, but the distance between a quiet, sedentary (perhaps anesthetized subject) and an aviator in flight or ground troops involves a tremendous leap of “technical courage”. We believe the technology and processing abilities today will allow for a total change in focus from trying to integrate a comprehensive sensing solution into a flight or ground helmet to one where the needed solution is not actually near the head or helmet. This insight changes algorithm design. A small, lightweight, and comfortable monitoring system might eventually be designed to continuously measure multiple physiological parameters in an effort to track operator state and hypoxia, e.g., from the arm alone. Sensors which detect SpO2, pulse/pulse rate, ECG, and skin temperature will be researched and evaluated for integration feasibility with a tactile vibrator for alerting the user to the suspicion of growing hypoxia. Novel and non-traditional sensor locations and technologies will be investigated as they impact data and algorithm design issues, and advanced signal processing techniques applied, and compared in this program for extensive technology leveraging.

However, all of this will be directly applicable to effective algorithm design. Each of the different measurements will be entered into a multi-parameter evolutionary prediction algorithm which outputs a numerical score that correlates to how prevalent any effects of hypoxia are to the user and to perhaps suggest or anticipate the onset of hypoxia based on trend data. Depending on the hypoxia algorithm's output, a signal potentially will be sent wirelessly to an alarming device integrated into the sensing platform wirelessly, or located in a key area of the users life support to vibrate which will alert the user if preventative action needs to be taken. No sensing system is infallible so key iteration rate considerations will need to be established in the algorithm design earlier than thought necessary to maximize hypoxia code output characteristics and iteration rates needed.

3.0 Technical Progress

*3.1 **Task 1 – Preliminary Research and Documentation***

This task has been completed. As data and additional information becomes available or uploaded to the FTP site we will make note of it in this section.

Dr. Shender uploaded additional data to the FTP site that included smaller time steps between data points. This data was used in evaluations and development discussed later in this report.

An additional publication was reviewed and is included below.

ASMARO D, MAYALL J, FERGUSON S. Cognition at altitude: impairment in executive and memory processes under hypoxic conditions. Aviat Space Environ Med 2013; 84: 1159 – 65.

Authors measured short-term and working memory capacity using Digit Span tasks, cognitive flexibility and selective attention using the Word-Color Stroop Task, executive functioning using Trailmaking A and B tests at baseline and simulated altitudes equal to 17,500 ft. and 25,000 ft. to study the affect of altitude exposure on cognitive tasks. While this study pertains to the aviation exposure some implications of ground operations are evident. Cognitive performance decrements were observed at both altitudes compared to control but the 17,500 ft. score differences with respect to control were not as larger as those at 24,000 ft. In several conditions the control versus 17,500 ft. results was not significantly different. Unfortunately for our purposes this study did not report any physiological data, not even SaO2, which one would have considered necessary for safety. One might imply an oxygen saturation level, but that is not useful or appropriate. The implication for lower altitude operations is that embedding some cognitive test parameter in an interaction will not likely be helpful in indicating loss of cognitive performance. Once again leading to the conclusion that a tripwire parameters like SaO2 at a predetermined level such as 85 to 80% may be sufficient to start corrective action. One interesting aspect of this work was that the authors reported that the subjects were largely unaware of their impairment and some actually thought they were performing well when in fact not performing well. Since the function of the ultimate device is to warn and advise, convincing the user that the device is correct and they are impaired may be a challenge.

3.2 Task 2 – Develop Parametric Predictive Models

Verification of the converted C code implementation had one final bug remaining at the end of the last reporting period. The bug has been eliminated and a number of test cases have been used to compare the results of the initial SIMULINK model to the converted C code model. The results shown in Table 1 indicate that the two models are equivalent, and any difference which may have been calculated is due to rounding and is not physiologically significant.

Table 1: Comparison of physiological outputs calculated with the initial model and the current model

		Former Model			Current Model			Difference		
		O2 SAT	PAO2	PACO2	O2 SAT	PAO2	PACO2	O2 SAT	PAO2	PACO2
0.21	0	100	99.5	39.3	100	99.5	39.1	0	0	0.2
0.21	10000	97	60	35	97	60	34	0	0	1
0.21	20000	74	34	29	74	34	29	0	0	0
0.21	30000	29	15	25	29	15	24	0	0	1
0.21	40000	3	2	21	3	2	21	0	0	0
0.4	10000	100	152	40	100	151	40	0	1	0
0.6	20000	100	152	40	100	152	40	0	0	0
0.8	30000	100	119	40	100	119	40	0	0	0
1	0	100	671	40	100	671	40	0	0	0
1	10000	100	440	40	100	440	40	0	0	0
1	20000	100	272	40	100	272	40	0	0	0
1	30000	100	154	40	100	154	40	0	0	0
1	40000	97	61	35	97	61	34	0	0	1

The final piece of the planned effort under this task was to refine the time dependent functions of the baseline algorithm. The need for this was evident after review the ROBD data provided by ONR. By analyzing the SpO2 data from Subjects 7 and 23 the following time depend functions will need to be added to the baseline algorithm:

- Time delay on the order of 40 seconds and a
- Decaying exponential of the form

$$K_1 + K_2 e^{-at}$$

Where,

- $K_1 + K_2$ is the initial value,
- K_1 is the steady state value and
- $1/a$ is the time constant of the decaying exponential and is on the order of 1 to 4 minutes.

The a term appears to be altitude (or at least altitude change) dependent and will take some additional work to model. The K terms can be found using the existing baseline model output.

Figures 1, 2 and 3 show the step responses for Subject 7 and Subject 23 along with the model that uses the above time dependent functions. The same time constant (3.7 minutes) was used in Figures 1 and 2, but a significantly shorter time constant (66 sec) was needed in Figure 3. The model results compare reasonably well to the Subject response data. The average response for the subjects was calculated and then an R^2 correlation was computed to evaluate the Model with the following results:

Table 2. Model R^2 Results

Step Response (feet)	**R^2 (Model compared to Subject 7 & 23 Average)**
0 to 10K	0.989
10K to 18K	0.970
10K to 25K	0.978

This approach appears promising for use as the time dependent functions in the baseline model.

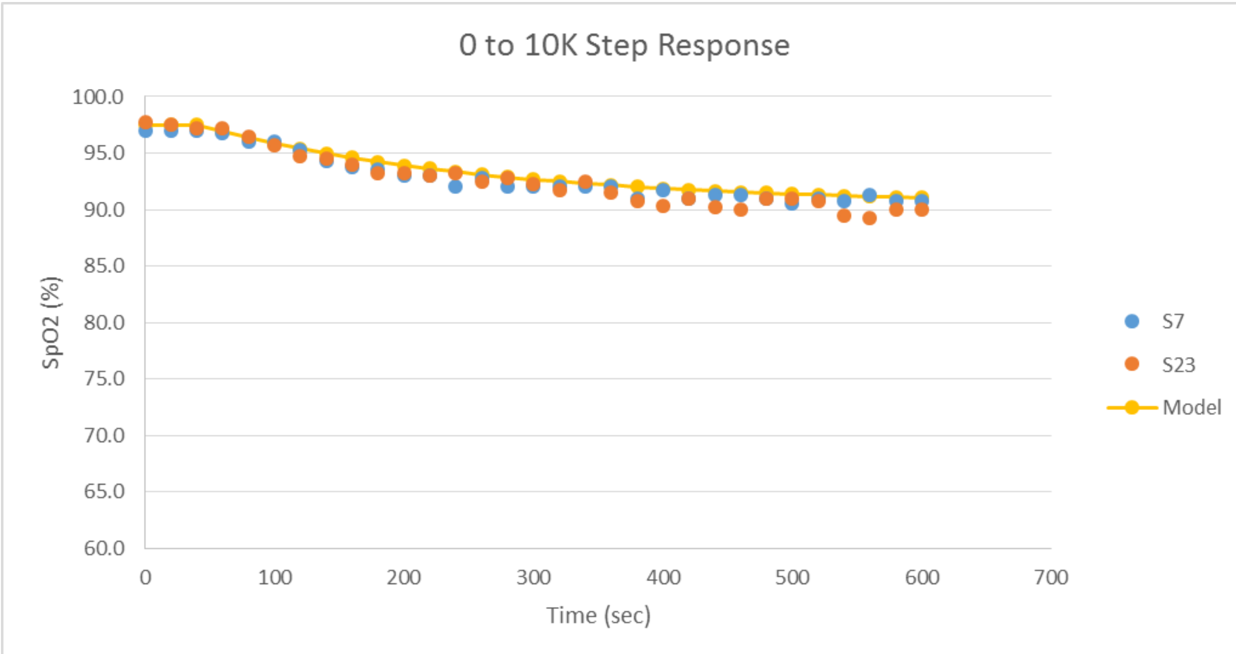


Figure 1. Step Response Estimation 0 to 10K Feet

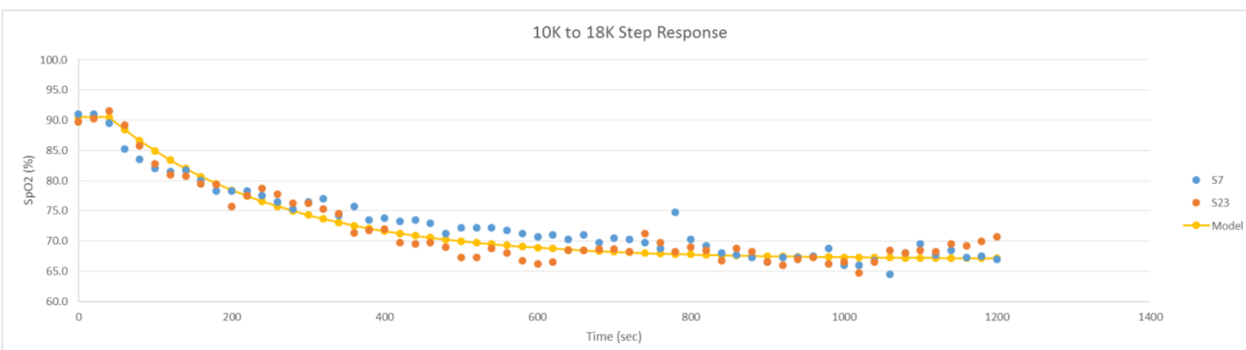


Figure 2. Step Response Estimation 10K to 18K Feet

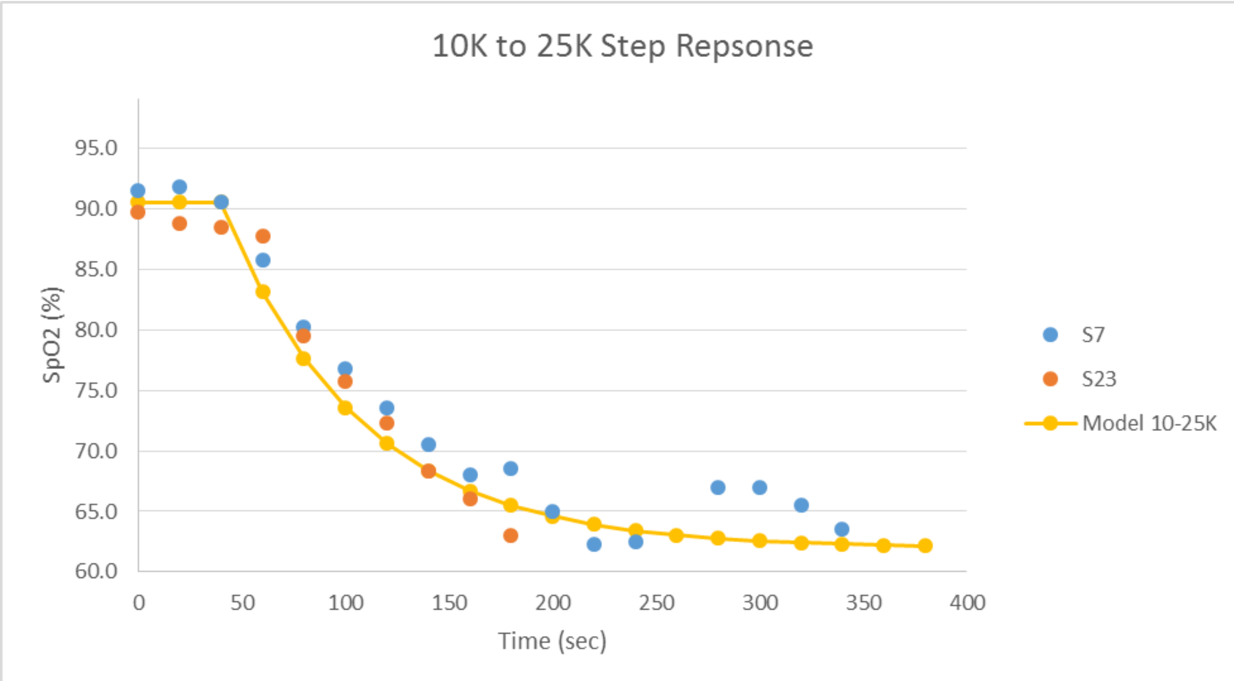


Figure 3. Step Response Estimation 10K to 25K Feet

This task is now considered complete.

3.3 Task 3 – Algorithm Development and Refinement

3.3.1 Task 3a – Update the USN Consciousness Model Implementation

The implementation of the working model must be converted from the Visual Basic for Application version to a further stripped down Basic language version and then translated into at least a C language implementation to be hosted on a small sized microcontroller or embedded system. A larger sized process system such as a tablet or smart phone level approach would still need this conversion under most implementation scenarios. The most up to date code was stripped of the Excel interface aspects and then converted to C language using BCX, a basic to C translator. The resulting C language code was modified and examined using the IAR embedded workbench set up for the MSP430 processor. The C code could be ported to any other processor with slight modification. Example items that were addressed are unnecessary library references and non-C language array indexing issues.

This processor choice was arbitrary but was influenced by Athena GTX's history of development with this device. The free IAR Workbench is code size limited and once all the errors were worked out one could go no further due to the larger code byte size. Code Composer from Texas Instruments was used to go further which allows for evaluation of various processor families within Texas Instruments product line.

The MSP430F67791 was chosen for its large Flash ROM size of 512KB and the code came out to be about 2KB over that size. For the sake of finding a microcontroller that would fit for further debugging and emulation, a TMS470F06607 was used under Code Creator which has 640KB total program flash memory. Under this processor the program easily fit with some lingering errors that can be fixed without issue. Reducing the code size further will be attempted by changing the size definitions and hard programming some items but emulation will be a prime importance to see test functionality. Now that the real embedded system program storage requirements are understood more clearly we can move on to Task 4 and refine the code to meet the program objectives. The modified USN Consciousness Model code is able to be implemented on a micro-controller platform.

3.3.2 Task 3b – Determine Model Deficiencies for Hypoxia

The HumMod model based on the Guyton work has been used to generate surrogate sensor data such as SaO2 for model evaluation, to explore the reaction of the human physiology to longer, less severe acute hypoxia exposures, and the ground solder physiological reaction to altitude operations. To insure we have the most validated simulation results, CAI has obtained the most current version of HumMod from HC Simulation LLC, the authorized agent for the University of Mississippi, for research purposes. CAI cannot distribute this model but other interested parties can obtain it from Dr. Hester at HC Simulation, LLC. This version of the model allows for creation of model time scenarios and specification of result time history timing. Further work will progress on generation of appropriate scenarios for physiological response assessment and model response evaluation.

Dr. Shender placed some raw data on the FTP site so that the 60 Hz SaO2 data could be run through the unconsciousness model. Some code modification was necessary to shift the data interval from 0.1 to 1 sec but this was accomplished and results for Dr. Shender's Subject 7 which also included composite cognitive/psychomotor scores from a prior upload was examined. Promising State prediction results were found for impairment and recovery by looking at this physiological and cognitive data.

Some interesting observations where made:

- A decrement in composite score is difficult to define with a 4 point moving average for the 18K feet data
- After return to ground altitude the model and subjective response indicated an impaired state. Not too sure what this means.
- Interestingly, administration of 100% oxygen and return to ground altitude improved the SaO2 response but composite score, predicted State and subjective response all indicate continued impairment and hypoxia effects indicating that SaO_2 alone may not be sufficient for neurological state prediction.

Time differences between data sources may render an exact alignment of SaO_2, predicted State, and composite score difficult but one can see that the corroboration is good for the one subject at 25,000 feet.

Further understanding of the composite score results and even a breakdown of constituent metrics at 18,000 feet are needed before any real indication of impairment can be made.

More subjects where the raw (60 Hz) SaO_2 data can be combined with the composite score data are needed for validation and tuning of thresholds. The details of the analysis are included below.

Two exposures, one to 18,000 and the other to 25,000 feet, were given. The session started at ground altitude and then progressed to 10,000 feet before the simulated ascension to the test altitude using a reduced oxygen mixture to simulate altitude.

Figure 4 shows Subjects 7's SaO_2 18,000 feet data and predicted values for active nodes, connected clusters and neurological state at a threshold of 100% loss of spanning clusters and at 80% loss of spanning clusters. Considering "impairment" as State "1", once the SaO_2 dropped below 90% an impaired state was indicated. With the threshold of 100% loss of a spanning cluster no loss of consciousness (LOC) was indicated but when changed to 80% an LOC was indicated as SaO_2 approached 60%.

A closer look is seen in Figure 5 and Figure 6 where the composite score from cognitive and psychomotor testing is also shown along with SaO_2 and State. A decrement in composite score is difficult to ascertain even with a 4 point moving average.

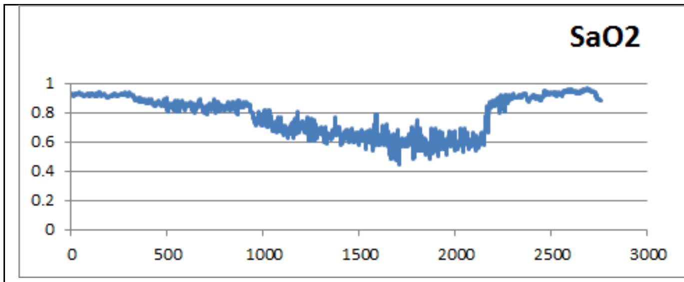
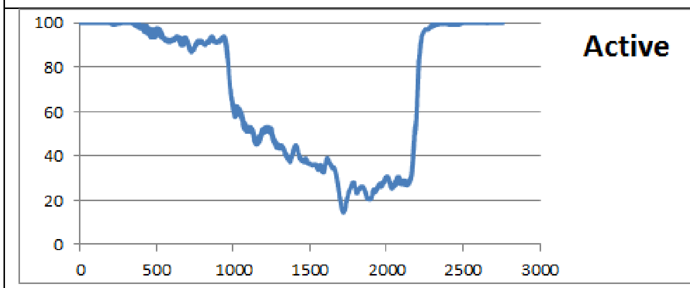
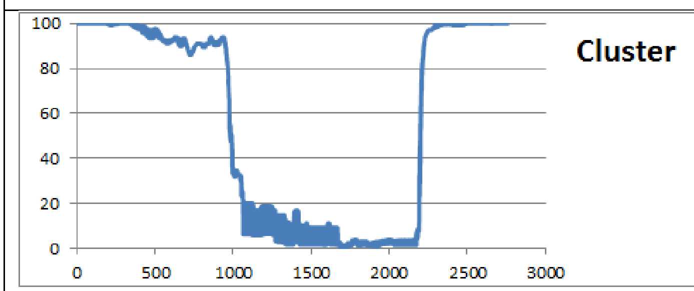
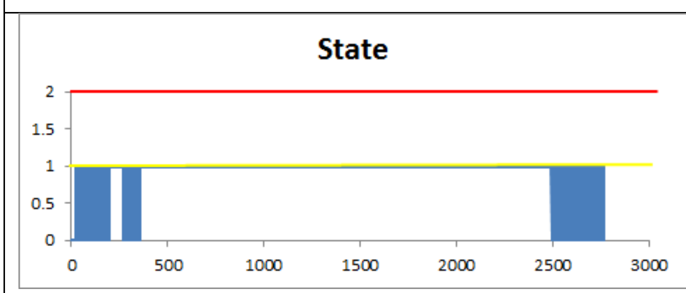
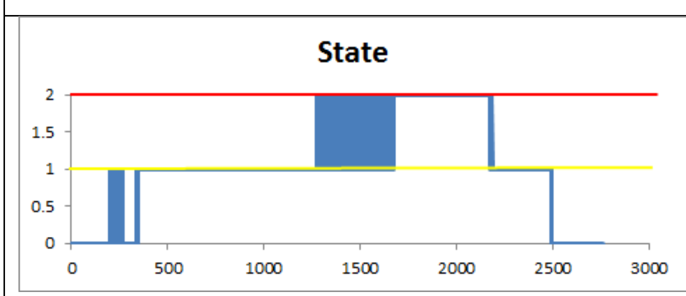
	Oxygen saturation
	Percentage of Active nodes
	Percentage of Nodes Connected.
	Cluster threshold at 0% for LOC. Impairment predicted but on “LOC” even with low percentage of connectivity. Wide blue areas represent uncertainty in non-impaired and impaired state.
	Cluster threshold at 20% for LOC. “LOC” predicted (none occurred) but span of blue between approximately 1200 and 1600 represent uncertainty in imparied and LOC states.

Figure 4 Subject 7 exposure to 18,000 simulated with the USN Consciousness Model

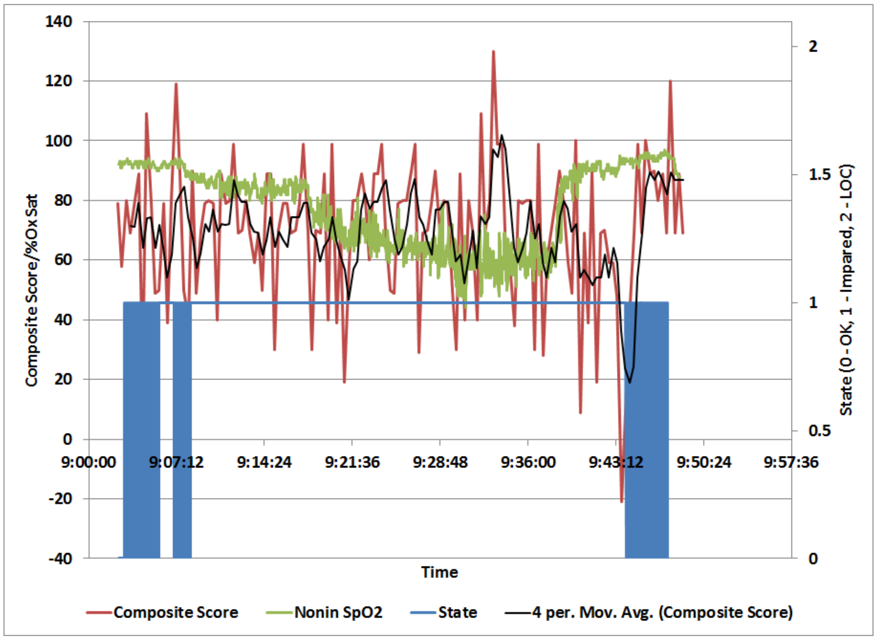


Figure 5 LOC threshold at 0% Connectivity for Subject 7 at 18,000 feet.

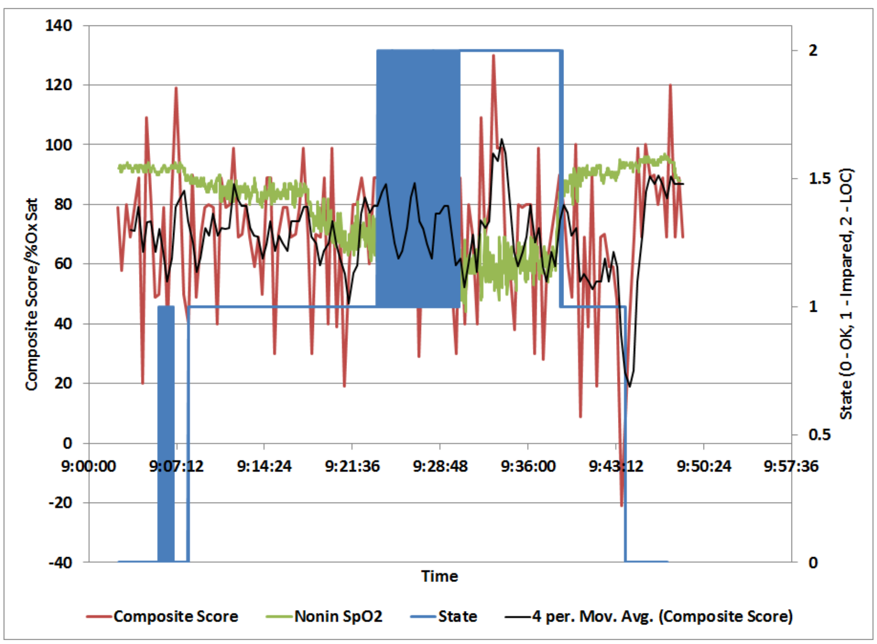


Figure 6 LOC threshold at 20% Connectivity for Subject 7 at 18,000 feet.

Table 3 shows the subjective response for Subject 7 where lightheadedness was indicated at times where significant loss of active nodes and connectivity were predicted.

Table 3 Experimental Subjective Response for Subject 7 at 18,000 feet

9:07:49	10,000	
	10,000	
9:17:57	18,000	
9:19:38	18,000	lightheaded
	18,000	
9:28:46	18,000	lightheaded
	18,000	
9:37:54	0	
9:40:16	0	lightheaded

Even after return to ground altitude the model and subjective response indicated an impaired state.

Figure 7 shows Subjects 7's SaO_2 25,000 feet data and predicted values for active nodes, connected clusters and neurological state at a threshold of 100% loss of spanning clusters and at 80% loss of spanning clusters. Considering "impairment" as State "1", once the SaO_2 dropped below 90% an impaired state was again indicated. With the threshold of 100% loss of a spanning cluster no loss of consciousness (LOC) was indicated but when changed to 80% an LOC was indicated as SaO_2 approached 60%. The loss of active nodes and spanning clusters was faster for the 25,000 feet exposure compared to the 18,000 feet exposure due to the more rapid drop in SaO_2.

Looking at Figure 8 and Figure 9 where the composite score from cognitive and psychomotor testing is shown along with SaO_2 and State. A marked drop in composite score is shown that corresponds to the onset of the oscillation between impaired and LOC states. Subject 7 was administered 100% Oxygen and while the SaO2 rose towards normal, the composite score and predicted State both showed impairment indicating that SaO_2 alone may not be sufficient for neurological state prediction.

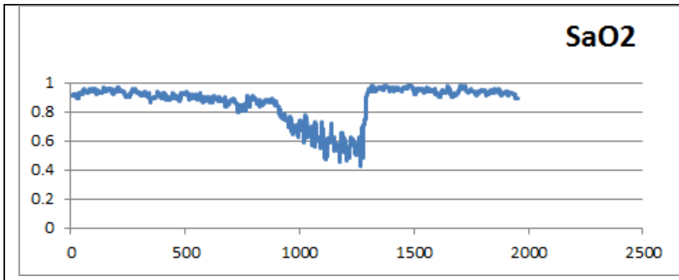
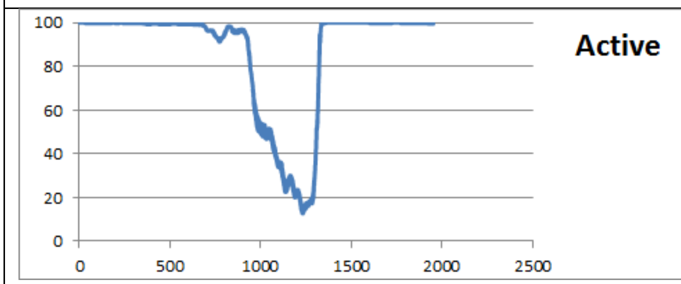
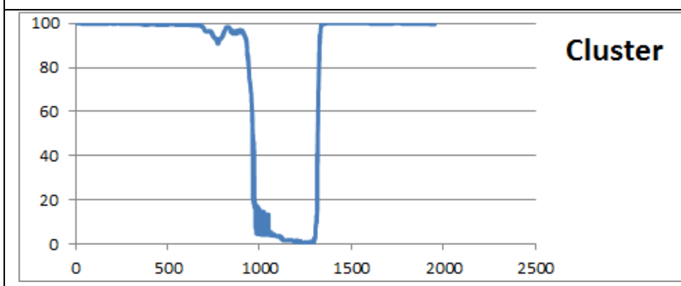
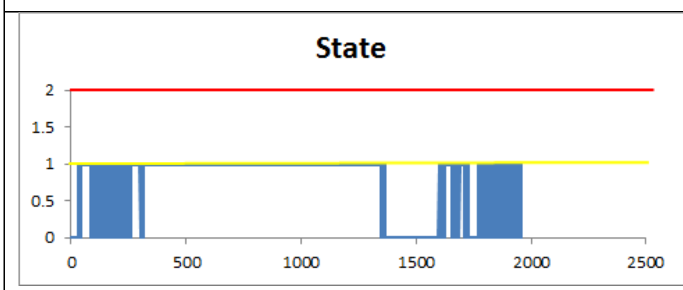
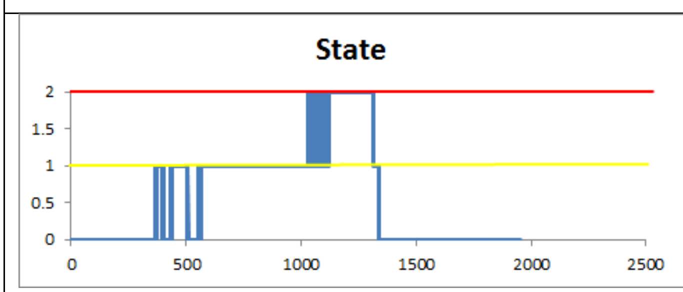
	Oxygen saturation
	Percentage of Active nodes
	Percentage of Nodes Connected.
	Cluster threshold at 0% for LOC.
	Impairment predicted but on “LOC” even with low percentage of connectivity. Wide blue areas represent uncertainty in non-impaired and impaired state.

Figure 7 Subject 7 exposure to 25,000 simulated with the USN Consciousness Model

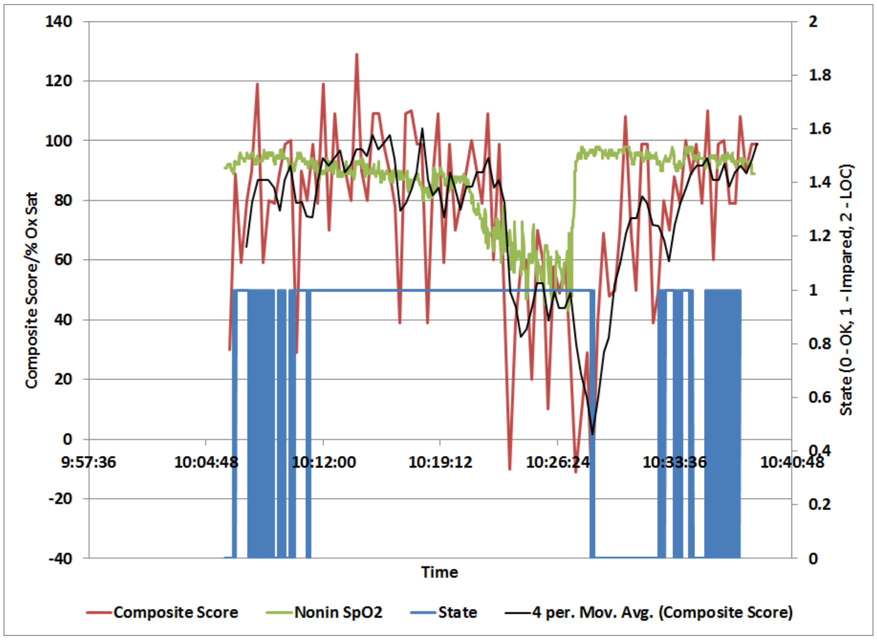


Figure 8 LOC threshold at 0% Connectivity for Subject 7 at 25,000 feet.

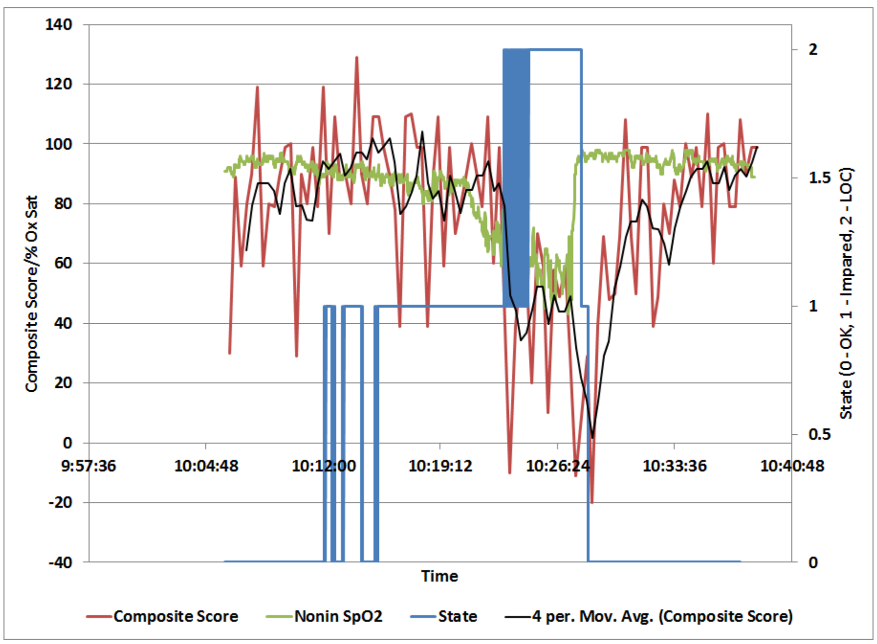


Figure 9 LOC threshold at 20% Connectivity for Subject 7 at 25,000 feet.

Table 4 shows the subjective response and study events for Subject 7 at 25,000 feet. Indications of lightheadedness and tingling fingers occur during predicted impairment and LOC periods.

Table 4 Experimental Subjective Response for Subject 7 at 25,000 feet

10:22:29	25000	lightheaded
10:22:49	25000	
10:23:09	25000	lightheaded
10:23:29	25000	
10:23:50	25000	
10:24:10	25000	tingling fingers
10:24:30	25000	
10:24:50	25000	lightheaded
10:25:11	25000	
10:25:31	25000	
10:25:51	25000	
10:26:11	25000	
10:26:32	25000	lightheaded
10:26:52	25000	
10:27:12	25000	
10:27:33	25000	tingling fingers
10:27:53	100% O2	brightness
10:28:13	100% O2	
10:28:33	0	
10:28:54	0	
10:29:15	0	
10:29:35	0	
10:29:55	0	LH & Tingling

Interestingly administration of 100% oxygen and return to ground altitude improved the SaO2 response but composite score, predicted State and subjective response all indicate continued impairment and hypoxia effects.

Time differences between data sources may render an exact alignment of SaO_2, predicted State, and composite score difficult, but one can see that the corroboration is good for the one subject at 25,000 feet. Further understanding of the composite score results and even a breakdown of constituent metrics at 18,000 feet are needed before any real indication of impairment can be made.

The above analysis indicated some promising results in terms of prediction of onset and recovery, but there were spans where the model exhibited regions of uncertainty and bounced back and forth between states. This aspect of the prediction was investigated to see if that behavior could be minimized or eliminated. Two factors influence this behavior. One factor is the threshold for a node being turned off within the connected node set and the other factor is the connectivity top to bottom in the node set. If the connectivity was zero then unconsciousness was declared in the original algorithm for GLOC but the model results displayed some possible computational features that might not drive the value to zero in the hypoxia only state, so altering this relationship could produce more sensitivity. Using the Subject 7 at 18,000 feet, these two factors, threshold and connectivity, were adjusted with positive results. The detailed analysis is included below.

The threshold was adjusted to 0.5, 0.69 (starting), 0.8, 0.85 and 0.9. The connectivity was adjusted between zero and < 20 for each of the threshold factors. The < 20 value was used based on preliminary adjustments where that value made a difference in predicted results.

Figure 10 shows the SaO_2 for this subject during the run. The SaO_2 starts out in the low 0.9 range likely due to the 10,000 ft. ascension at the beginning.

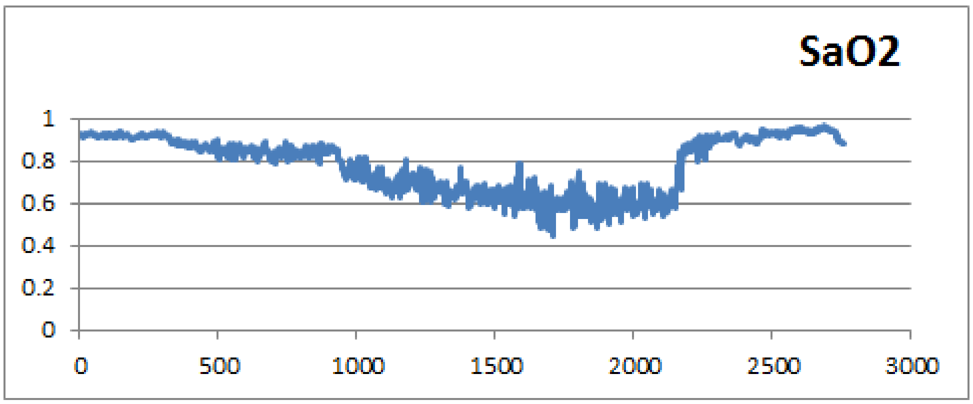
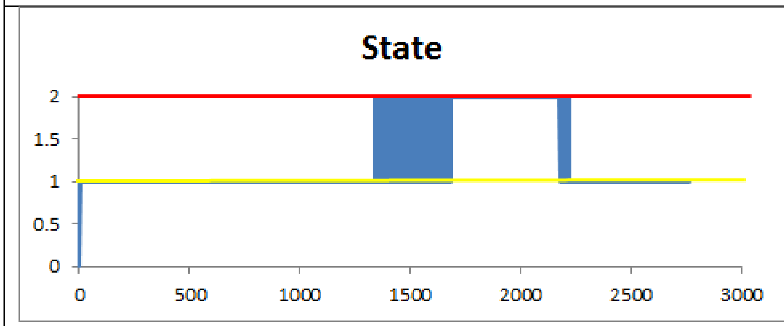
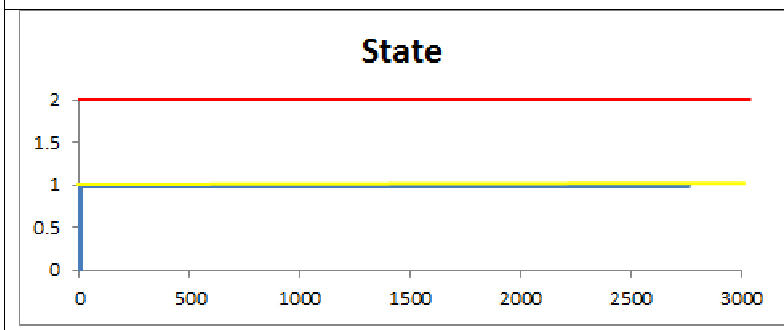
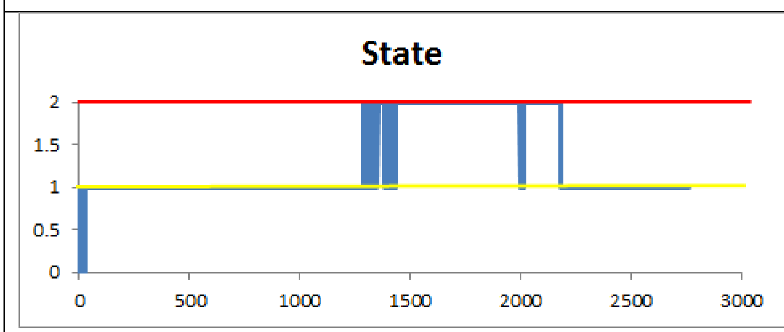
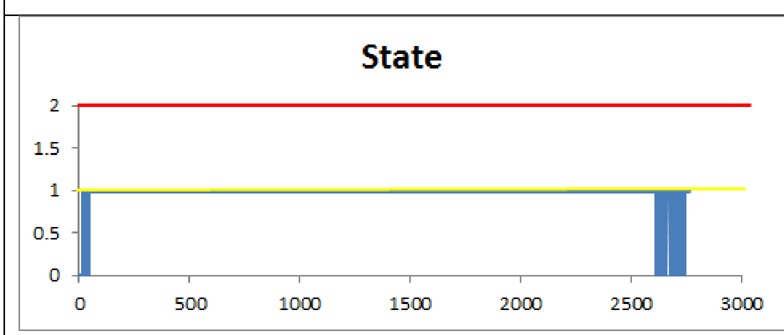


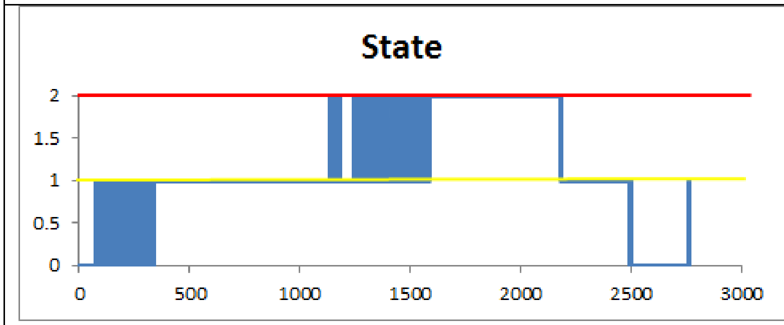
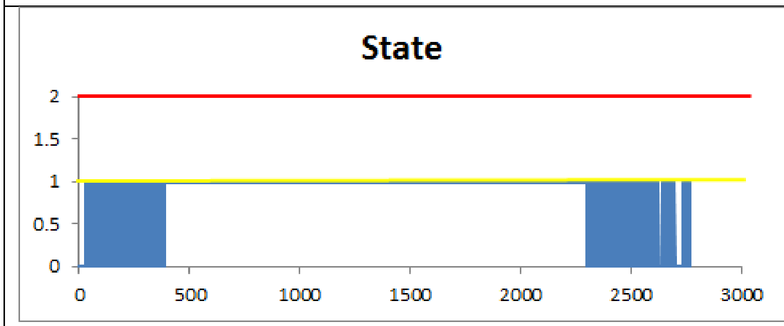
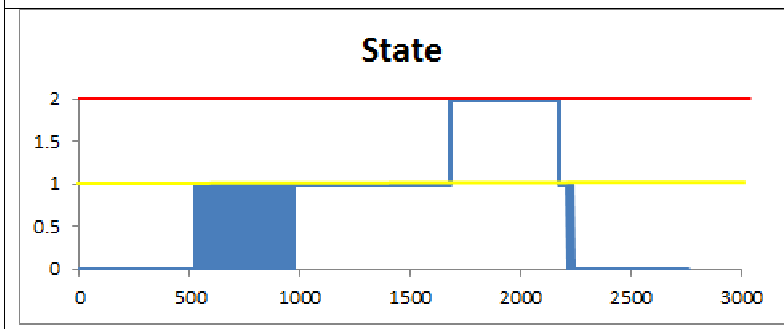
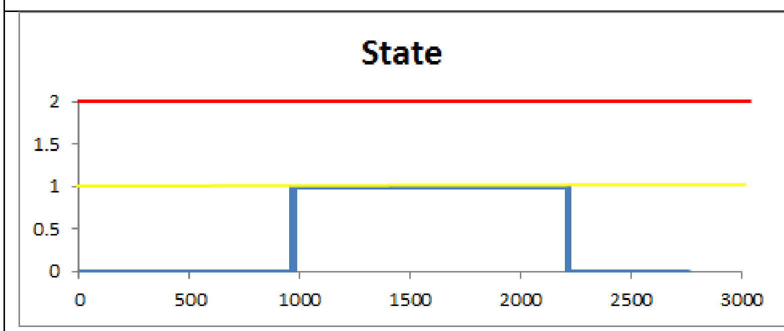
Figure 10 Subject 7 SaO_2 values at 18,000 feet. (Horizontal axis – time (sec))

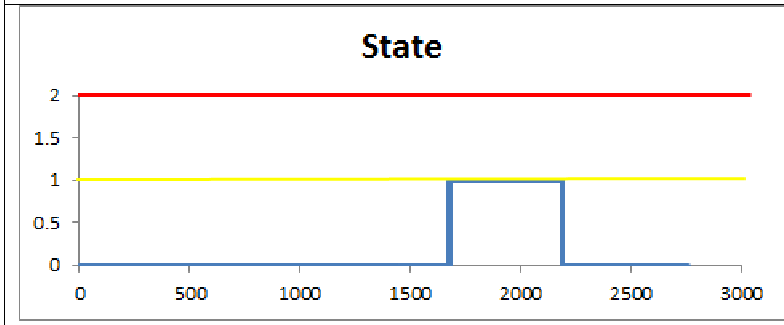
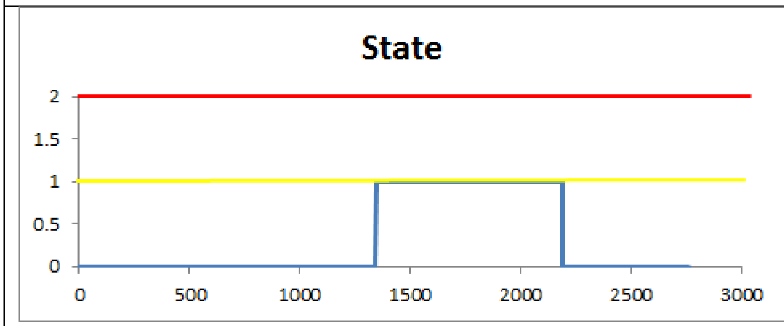
At approximately 500 seconds the SaO2 value drops to 85% and drops below 80% at 937 seconds. These values are significant based on clinical factors but also that SaO_2 monitors may be less reliable or at least not calibrated below 80%.

Table 5 shows the "State" prediction results from the model where the threshold and connectivity were varied as indicates. A State of zero indicates no impairment, a "1" (yellow line) indicates impairment and a "2" (red line) indicates unconsciousness. As Subject 7 did not experience unconsciousness moving the connectivity parameter to < 20 appears unwarranted since it tended to predict a loss of consciousness. With the threshold value at 0.9 a prediction of impairment was immediately indicated and as the threshold value was lowered, the impairment prediction shifted in time but with the oscillation in impairment prediction as noted before. The one combination of threshold and connectivity that had the least amount of uncertainty was a threshold of 0.69 and a connectivity of zero. While this removed the unwanted behavior, this combination did not predict impairment until SaO_2 crossed below 80% but did show the demonstrated lag in predicting non-impaired state after the SaO_2 had recovered to baseline.

Table 5 Decision value variations for the Neurological State Model

State Prediction	Threshold	Connectivity
	0.9	< 20
	0.9	0
	0.85	< 20
	0.85	0

State Prediction	Threshold	Connectivity
	0.8	< 20
	0.8	0
	0.69	< 20
	**0.69**	**0**

State Prediction	Threshold	Connectivity
	0.5	< 20
	0.5	0

Horizontal axis is time in seconds

Figure 11 shows a comparison of SaO_2 with two simulation output parameters, active and cluster mass for the Subject 7, 18,000 ft. run with threshold at 0.69 and connectivity at zero. Active indicates the percentage of nodes active and cluster mass indicated the percentage of nodes connected.

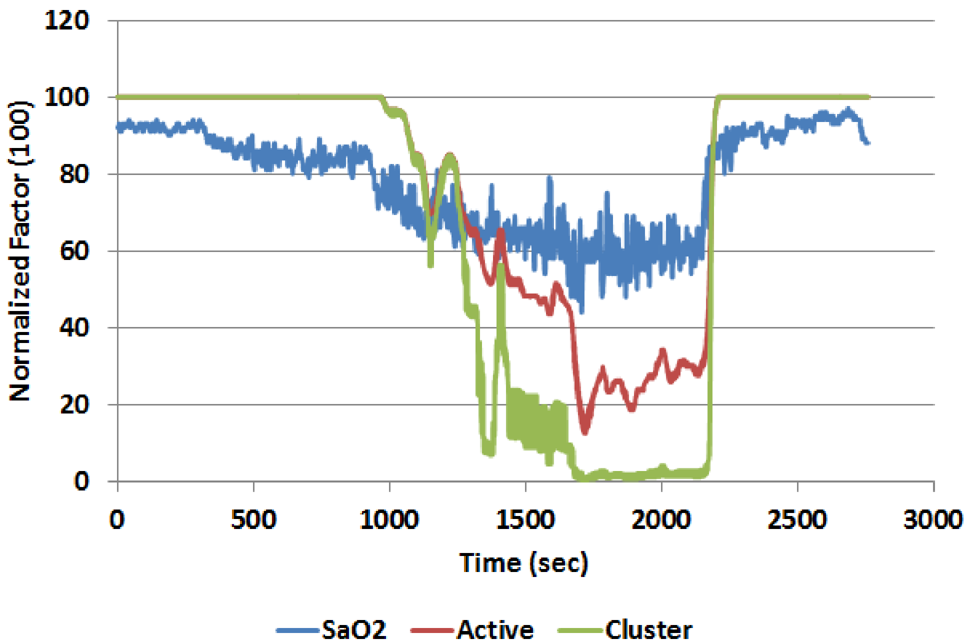


Figure 11 Simulation output values, active and cluster mass, compared to SaO_2

Interestingly the two parameters track each other starting to decrease when SaO_2 goes below 80% but diverge around 1250 seconds. The two parameters track with SaO2 recovery almost exactly and do not show the demonstrated lag in performance recovery. Using these predicted parameters may not prove useful in neurological state prediction.

More subjects where the raw (60 Hz) SaO_2 data can be combined with the composite score data are needed for validation and turning of thresholds that were analyzed above.

3.3.3 Task 3c – Determine Model Deficiencies - Other

Several existing models and algorithms from recent and on-going programs at Athena (ACCS state assessment, Hammerhead™ and mini-Medic®) have been evaluated for their applicability to this project. The following summarizes the current findings.

Autonomous Combat Casualty Care System (ACCS) – The current algorithm development under the ACCS program includes a comprehensive multi-parameter medical status determination on the casualty from point of injury (POI) to definitive care. This diagnostic algorithm includes near real time non-invasive assessments with closed loop control of therapeutics which includes ventilation, fluid resuscitation and anesthetics/analgesics. The coding underway for the program includes remote care providers interfacing directly with both the diagnostics and therapies via wired on site (Tablet) and wireless off site providers and subject matter experts. As the casualty is transported from the POI transitions to environmental extremes of altitude exacerbate the pressure, vibratory interferences, and temperature of the patient and system. In addition specific diagnosis and therapies for suspected mild to moderate TBI are included. These in turn impact therapies. These codes are directly relevant to the Phase 1 HAMS CASEVAC application.

Hammerhead – Athena is waiting for permission to use algorithms developed under this project in HAMS. These algorithms are particularly applicable is workload and fatigue at altitude when hypoxia may be apparent. The primary application is ground troop operations.

Mini-Medic – Mini-Medic is a multi-parameter, FDA cleared monitor that incorporates a summary alarm feature called Murphy Factor. Murphy Factor is a concept for integrating multiple parameters into a single output alarm signal. Although the exact algorithm would need to be modified for HAMS a similar approach is applicable to this project and is applicable to both the ground operations and CASEVAC applications.

3.4 *Task 4 – BETA Model Software Development/Definition*

The final baseline task (Task 4) has been started. Software algorithms will be developed through three sequential iterations that will progressively refine a prediction for hypoxia and near-hypoxia conditions. The focus on implementation in a memory-limited, bit-constrained microcontroller will remain a top priority. For each iteration the algorithms and software will be evaluated using existing data.

3.5 *Task 5 – (Option) – Concept System Refinement*

This option has not been exercised. This task is scheduled to begin June 2014.

3.6 *Task 6 - Deliverables*

See Section 5.2 below.

4.0 Financial Progress

The total base budget for the HAMS program is $385K plus an option of $71K. The contractually obligated amount in FY2013 towards the total budget is $170K. The contractually obligated amount in FY2014 towards the total budget is $160K. Costs incurred to date through this performance period are $230K or approximately 70% of total obligated funding.

We project that we will need additional funding in March 2014. If funding is secured for the remainder of the program the estimate to complete remains at the original budget for the program ($385K plus an option of $71K if this option is exercised).

The tables below summarize the costs incurred to date against the FY 2013 and FY 2014 obligated funding to date ($170K and $160K, respectively). A more detailed spread sheet has been included in the Appendix, Section 9.1.

4.1 FY2013 Funding ($170K)

Month	HAMS Projected (%)	ONR Benchmarks FY13 Funding (%)	HAMS Actual (%)	Benchmark Delta (%)	Comments
AUG	41	49	58	+9	Additional funding will be needed in NOV to fulfill SOW expectations.
SEP	85	56	81	+25	Additional funding will be needed in NOV to fulfill SOW expectations.
OCT	100	57	93	+35	Additional funding will be needed in NOV to fulfill SOW expectations.
NOV	100	63	100	+36	FY 2013 funds have been exhausted.

4.2 Benchmarks for FY2014 Funding ($215K and 160K Applied)

Month	HAMS Projected (%)	ONR Benchmarks FY13 Funding (%)	HAMS Actual (%)	Benchmark Delta (%)	Comments
OCT	0	0	0		
NOV	0	1	0		
DEC	27	3	17	+15	FY2014 Funds Received ($160K)
JAN	60	6	37	+31	
FEB	82	12			
MAR	101	20			$160K Funds will be exhausted
APR	116	23			
MAY	134	29			

*Plan % of this column is based on remaining contract amount 215K as negotiated with partial funding of 160K applied.

5.0 Schedule and Deliverables

5.1 Schedule

Tasks	CY 2013						CY 2014						
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	APr	May	Jun	Jul
1. Preliminary Research and Documentation													
2. Develop Parametric Predictive Models													
3. Algorithm Development and Refinement													
4. BETA Model Software Development/Definition													
5. Concept System Refinement (Option)													
6. Deliverables													
Monthly Updates													
Quarterly Reports													
Final Report													
Beta Software													
Trade-off & Preliminary Specification (Option)													

Progress/Completed
Planned

5.2 Deliverables

5.2.1 Monthly Updates

Six Monthly updates have been submitted to ONR for August, September and October of 2013.

5.2.2 Quarterly Reports

The following quarterly reports have been submitted to ONR:

- A001-1, Report for the period July 24, 2013 to October 31, 2013 and
- A001-2, Report for the period November 01, 2013 to January 31, 2014.

5.2.3 Final Report

Not due until May 2014.

5.2.4 BETA Software

Not due until May 2014.

5.2.5 Option – Trade-off Analysis and Preliminary Specification

This option has not been exercised.

6.0 Conclusion

The Hypoxia Monitoring, Alert and Mitigation System (HAMS) program is progressing as expected with no technical issues to report. Work has completed on Tasks 1, 2 and 3. Task 4 began in January 2014 and the Task 5 option (not yet exercised) would begin in June 2014.

Partial FY2014 program funding remains an issue, with additional funds needed in March 2014 to continue the effort without significant impact to the program.

The concentrated effort on the literature search activity (Task 1) has been completed. . Reasonably so, this task really never ends as new works constantly will be published or become available through professional connections. A File Transfer Protocol (FTP) site has been created to share references and data among the team members and Office of Naval Research (ONR). As data and additional information becomes available or uploaded to the FTP site we will address them as necessary.

The baseline parametric hypoxia modeling effort (Task 2) has been completed. A model to predict %O_2 saturation, aircrew state, alveolar pressure of oxygen (PaO_2) and alveolar pressure of carbon dioxide ($PaCO_2$) has been converted over to the C programming language. This will allow the algorithm to eventually run on a micro-controller. Additionally the time based algorithms have been adjusted to better represent the physiological response of the human to high altitude hypoxic events.

The conversion of the United States Navy (USN) Consciousness Model (Task 3) has been completed. Initial verification and sensitivity analysis has shown positive results and the code has been reduced to a size and complexity that will run on a modest microcontroller. The addition of a hypoxia component to the acceleration component of the model has demonstrated good results. Model and threshold refinement will continue with additional data sets in Task 4.

The final baseline task (BETA Model Software Development/Definition – Task 4) has been started. Software algorithms will be developed through three sequential iterations that will progressively refine a prediction for hypoxia and near-hypoxia conditions. The focus on implementation in a memory-limited, bit-constrained microcontroller will remain a top priority. For each iteration the algorithms and software will be evaluated using existing data.

7.0 Recommendations

We recommend that the program continue as scheduled assuming the remaining funding is obligated to the contract. We are encouraged that the ONR continues to pursue the remaining funding on Phase 1 in a timely manner to keep the team together.

8.0 References

Not Applicable. See Section 3.1 for additional literature review results relevant to HAMS.

9.0 Appendix

9.1 Detailed Financial Spreadsheets (PDF)

H.A.M.S. FUND YEAR 2013 / 2014 COMBINED CONTRACT# N00014-13-C-0323 EFFECTIVE 7/24/2013 to 5/24/2014		EXPENDITURE % BY MONTH based on 330K	30.23%	41.98%	48.33%	51.68%	59.87%	69.64%	69.64%	69.64%	69.64%	69.64%	69.64%	69.64%
HAMS FY 2013	CUMULATIVE SPENT TO DATE	% of Total FUNDS Expended BASED on Total Program	MO 1 - AUG	MO 2 - SEP	MO 3 - OCT	MO 4 - NOV	MO 5 DEC	MO 6 - JAN	MO 7 - FEB	MO 8 - MAR	MO 9 - APR	MO 10 - MAY	MO 11 - JUN	MO 12 - JUL
COST INCURRED	$ 229,799.11	50.38%	$ 99,767.22	$ 38,756.79	$ 20,956.96	$ 11,079.10	$ 27,023.01	$ 32,216.03	$ -	$ -	$ -	$ -	$ -	$ -

			Task 1, 2, 3, 6	Task, 1, 2, 3, 6	Tas, 2, 3, 6	Task, 3, 6	Task 3, 6	Task 3, 4, 6	Task 4, 6	Task 4, 6	Task, 4, 6	TASK 4,6	option task 5	option task 5
HAMS FY 2013	BUDGET 1	% of Total BUDGET Expended	MO 1 - AUG	MO 2 - SEP	MO 3 - OCT	MO $ - NOV	MO 5 - DEC	MO 6 - JAN	MO 7 - FEB	MO 8 - MAR	MO 9 - APR	MO 10 - MAY	MO 11 - JUN	MO 12 - JUL
TOTAL BUDGET	$ 170,056.58	100.00%	$ 70,935.88	$ 74,928.89	$ 24,191.81	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
		Projected expenditure % based on 170K budget	41.71%	85.77%	100.00%	100.00%	100.00%	100.00%	100.00%					

HAMS FY 2014	BUDGET 2	% of Total BUDGET Expended	MO 1 - AUG	MO 2 - SEP	MO 3 - OCT	MO 4 - NOV	MO 5 - DEC	MO 6 - JAN	MO 7 - FEB	MO 8 - MAR	MO 9 - APR	MO 10 - MAY	MO 11 - JUN	MO 12 - JUL
TOTAL BUDGET	$ 286,040.19	100.00%	$ -	$ -	$ -	$ -	$ 44,196.87	$ 53,243.55	$ 34,325.33	$ 30,929.78	$ 24,021.05	$ 28,253.63	$ 37,392.10	$ 33,677.89
		Projected expenditure % based on $286K	0.00%	0.00%	0.00%	0.00%	15.45%	34.07%	46.07%	56.88%	65.28%	75.15%	88.23%	100.00%

10.0 List of Symbols, Abbreviations and Acronyms

[O2]	Concentration of Oxygen
AMS	Altitude Mountain Sickness
ANS	Autonomic Nervous System
COPD	Chronic Obstructive Pulmonary Disease
DSP	Digital Signal Processing
ECG	Electrocardiogram
EPO	Erythropoietin
FDA	Food and Drug Administration
FTP	File Transfer Protocol
HAMS	Hypoxia Monitoring, Alert and Mitigation System
HRV	Heart Rate Variability
ONR	Office of Naval Research
PaCO2	Alveolar Pressure of Carbon Dioxide
PaO2	Alveolar Pressure of Oxygen
RER	Respiratory Exchange Ratio
ROBD	Reduced Oxygen Breathing Device
SaO2	Arterial Oxygen Saturation Measured via CO-Oximeter
SpO2	Arterial Oxygen Saturation Measured via Pulse-Oximeter
TAILSS	Tactical Aircrew Integrated Life Support System
TUC	Time of Useful Consciousness
USN	United States Navy

11.0 Distribution List

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